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1 CLAIMS

- 2
- 3 1. A method for improving the efficacy of drug
4 trials, the method comprising the step of
5 screening samples from potential participants for
6 the genetic basis of Gilbert's Syndrome and
7 eliminating or including potential participants in
8 a drug trial in the knowledge of them possessing
9 or not possessing the genetic basis of Gilbert's
10 Syndrome.
- 11
- 12 2. A method as claimed in claim 1 comprising the
13 steps of:
- 14
- 15 a) taking a sample from each potential
16 participant in a drug trial,
- 17
- 18 b) screening the samples for the genetic basis
19 of Gilbert's Syndrome,
- 20
- 21 c) identifying participants having the genetic
22 basis of Gilbert's Syndrome, and
- 23
- 24 d) proceeding with drugs trials in the knowledge
25 of participants possessing or not possessing
26 the genetic basis of Gilbert's Syndrome.
- 27
- 28 3. A method as claimed in claim 1 or 2 wherein the
29 sample is chosen from blood, buccal smear or any
30 other sample containing DNA from the potential
31 participants.
- 32
- 33 4. A method as claimed in any of the preceding claims
34 further comprising the step of eliminating
35 participants having the genetic basis of Gilbert's
36 Syndrome from a drugs trial.

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- 1 5. A method as claimed in any of claims 1 to 3
2 wherein the method comprises the further step of
3 selecting only participants having genetic basis
4 for Gilbert's Syndrome for a drugs trial.
- 5
- 6 6. A method as claimed in any of claims 1 to 3
7 further comprising the step of interpreting the
8 results of the drugs trial in the knowledge that
9 certain participants have Gilbert's Syndrome.
- 10
- 11 7. A method as claimed in any of the preceding claims
12 wherein the method comprises the steps of:
 - 13 a) isolating DNA from each sample,
 - 14 b) amplifying the DNA inner region indicating
15 the genetic basis for Gilbert's Syndrome,
 - 16 c) isolating amplified DNA fragments, and
 - 17 d) identifying individuals having the genetic
18 basis of Gilbert's Syndrome.
- 19
- 20
- 21 8. A method as claimed in any of the preceding claims
22 wherein the DNA is amplified using the polymerase
23 chain reaction (PCR) using a radioactively
24 labelled pair of nucleotide primers.
- 25
- 26
- 27
- 28
- 29 10. A method as claimed in any of claims 7 to 9
30 wherein the DNA region indicating the genetic
31 basis of Gilbert's Syndrome is the gene encoding
32 UDP-glucuronosyltransferase (UGT).
- 33
- 34 11. A method as claimed in any of claims 7 to 10
35 wherein the DNA to be amplified is in an upstream
36 promoter region of the UGT 1*1 exon 1.

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- 1 12. A method as claimed in any of claims 7 to 11
2 wherein the DNA to be amplified includes the
3 regions between -35 and -55 nucleotides at the 5'
4 end of UGT 1*1 exon.
5
6 13. A kit for screening individuals participation in
7 drug trials, the kit comprising primers for
8 amplifying DNA in the region of the genome
9 indicating the genetic basis of Gilbert's
10 Syndrome.
11
12 14. Primers for use in a method as claimed in any of
13 the preceding claims including primer pairs, AB or
14 CD as follows:
15
16 A/B (A, 5'-AAGTGAACCTCCCTGCTACCTT-3',
17 B, 5'-CCACTGGGATCAACAGTATCT-3') or
18 C/D (C, 5'-GTCACGTGACACAGTCAAAC-3';
19 D 5'-TTTGCTCCTGCCAGAGGTT-3').